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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,012	02/27/2002	Christopher P. Carson	50642/270981	6691

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EXAMINER	
WEBB, SARAH K	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,012	CARSON, CHRISTOPHER P.	
	Examiner	Art Unit	
	Sarah K Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *21-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-20, drawn to a method for total knee arthroplasty, classified in class 623, subclass 908.

   II. Claims 21-29, drawn to a surgical apparatus, classified in class 600, subclass 424.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus could be used for a different type of surgery, such as spinal surgery.

3. During a telephone conversation with Michael Bertelson on 5/24/04 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/084,278. Although the conflicting claims are not identical, they are not patentably distinct from each other because the steps of the process and structural limitations are the same, although this application '012 is directed to total knee arthroplasty and the application '278 is directed to unicompartmental knee arthroplasty.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6,8,10-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,682,886 (Delp et al).

Delp discloses a method for knee arthroplasty:

(a) First, a locator, which may be a CT scan, x-ray device, or MRI (column 15, line 23) obtains data corresponding to structure of a body part (column 8, lines 32-38). A fiducial is attached to the body part (column 18, lines 3-16). A registration means (750), or part of the locator, can also be tracked by the position sensor (column 15, lines 15-20). Both the femur and tibia are registered (column 16, line 18 and column 17, line 62).

(b) Next, a surgical instrument (femoral jig) is attached to part of the locator (670) so that it can be tracked by the position sensor (column 19, lines 24-30).

(c) a computer (770) tracks the position and orientation of the sensors (column 15, line 5).

(d) an image is displayed on a monitor (790) that shows the position and orientation of the surgical instrument (jig) relative to the body (column 20, lines 6-10).

(e) the surgical instrument (jig) is navigated into alignment and attached to the body (column 20, lines 25-26).

(f) the femur and tibia are "modified", using the jigs (column 21, lines 6-30).

(g) the surgeon assessing the performance of the joint using images (column 21, lines 55 through column 22, line 7).

Regarding claim 2, a probe is used to register a body part (column 15, line 17). Regarding claim 3, the procedure is directed to both the femur and tibia. Regarding claim 6, Delp discloses many different types of position sensors in lines 15-20 of column 15. Regarding claim 8, Delp further includes the steps of registering a trial component (femoral or tibial) after the jig has been removed, tracking the trial component, displaying the position of the trial component, and installing the trial component (column 21, line 55 through column 22, line 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delp in view of US Patent No. 5,733,292 (Gustilo et al.).

Delp includes all the limitations of claims 15 and 17, except for performing soft tissue balancing and release while the trial implant is in place. Delp only performs soft tissue testing with the final implant in place (column 22, lines 10-19). Gustilo discloses a method for total knee arthroplasty that includes the use of a noninvasive alignment device (column 14, lines 45-65). Gustilo teaches that soft tissue balancing tests should

be performed while a trial implant is placed in the knee joint so that soft tissue releases can be performed to adjust the alignment and balance of the joint (column 14, lines 10-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform soft tissue balancing tests and releases while the trial components of Delp are placed in the knee, as Gustilo teaches that this allows for the stability and alignment of the knee to be optimized by releases. The trial components of Delp are being tracked by sensors and a locator, so the trial components are inherently being tracked during balance testing.

8. Claims 9, 18, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delp in view of US Patent No. 6,226,548 (Foley et al.).

Delp includes imitations of claim 9, but fails to include the steps of discontinuing tracking with the trial component fiducial and initiating tracking of the trial component using the body fiducial. Foley discloses a procedure of image-guided surgery using fiducials attached to a probe and a fiducials attached to the body. Foley teaches that after an implant is registered using the fiducial attached to the probe, tracking can be discontinued with this component and initiated using the fiducial attached to the body (column 8, line 48 through 60). Since Delp includes fiducials attached to both the trial component and the body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the process of Delp the steps of (a) discontinuing tracking with the trial component fiducial and (b) initiating tracking with the body part fiducial, as Foley teaches that this is another way to track a surgical component in image-guided surgery.

Delp includes all the limitations of claims 18 and 20, except for tracking the position of an implant with a fiducial. Delp does include tracking the position of trial implants, but does not track the final implants (550,560). Delp also includes the step of testing the soft tissue (ligaments) when the implant is installed (column 22, lines 10-19). Foley teaches that implants should be registered and tracked during image-guided surgery (column 9, lines 30-35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include registration and tracking of the implants of Delp, as Foley teaches that these steps should be included in image-guided surgery in order to correctly place the components within the body. Regarding claim 20, it would have been obvious to include the steps of a) discontinuing tracking with the implant fiducial and (b) initiating tracking with the body part fiducial as explained above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
05/27/04

DAVID O. REIP
PRIMARY EXAMINER